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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,663	12/06/2000	Michael J. Hageman	01-677	8091
7590 10/07/2003 PHARMACIA CORPORATION PATENT DEPARTMENT - 04B 800 N LINDBERGH BOULEVARD ST LOUIS, MO 63167			EXAMINER SHAMEEM, GOLAM M	
			ART UNIT 1626	PAPER NUMBER

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/730,663	Applicant(s) HAGEMAN ET AL.	
	Examiner Golam M M Shameem	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 2-14 and 16-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-35 are pending in the application. Receipt is acknowledged of applicant's response to Office action, filed on July 17, 2003 and that has been entered.

Response to Election/Restriction

Applicant's election **without** traverse of Group I, which includes claims 1 and 15 in paper No.9 filed on March 25, 2002, is acknowledged. Therefore, claims 2-14 and 16-35 are withdrawn from consideration by the Examiner under 37 C.F.R. 1.142 (b) as directed to non-elected subject matter. The requirement for restriction in Paper No. 6 is deemed proper and is therefore made FINAL.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Response to Arguments

Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tally *et al* (US Pat No 5,466,823) and further in view of Stavchansky *et al* (1990) of record and the rejection has been maintained for the reasons given in the last office action (paper No. 13). Applicant's arguments have been fully considered but are not deemed persuasive because Applicants' arguments unsupported by objective and competent factual evidence are entitled to little weight. *In re Greenfield* 197 USPQ 227. *In re Lindner* 173 USPQ 356. Applicant alleges, "amorphous celecoxib does not represent a mere change of form" (Response, page 6) and therefore, "*a prima facie* case of obviousness has not been made" (Response, page 2).

This assessment is speculation on applicant's behalf because one of ordinary skill in the art deemed to be aware of all the pertinent art in the field. Stavchansky *et al* (1990) teach that

amorphous solids will, in general, be better absorbed than will crystalline ones (lines 11-12, page 463) and amorphous state generally reduce the particle size of the drug and result in a faster rate of dissolution than occurs with a crystalline form (lines 5-7, page 465). The differences between the instant claims and the prior art references are so negligible, that one of ordinary skill in the chemical art would expect slight variations (for example, changing the physical state of a known compound, such as crystalline to amorphous form) to be within the expected purview of 35 U.S.C. 103(a). The disclosure of Tally *et al* and further in view of Stavchansky *et al* (1990) teach several combinations that would easily place Applicants' invention in possession of the public at the time of Applicants' invention was filed. Therefore, an ordinary artisan would have been motivated to prepare amorphous forms of a known crystalline compound with a reasonable expectation that such changing the forms/state of a compound would results compound of similar pharmaceutical activity. Only a reasonable expectation of success, not absolute predictability, is necessary for a conclusion of obviousness. *In re Longi*, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Also, mere change of form in and of itself does not disclose novelty. *Ex parte Conn and Norman*, 119 USPQ 388, 1956. In the absence of objective evidence showing an unexpected result, the obviousness rejection is deemed to be proper and hence, this rejection must be maintained.

Therefore, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (703) 305-0116. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703) 308-4532. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1


Joseph K McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1

October 1, 2003